

510(K) SUMMARY

SEP 25 2012

Corentec Co., Ltd.**BENCOX[®] Forte & BENCOX[®] Delta**4th June, 2012**ADMINISTRATIVE INFORMATION**

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Bencox Forte & Bencox Delta
Common Name: Femoral Head Prosthesis
Classification Regulations: 21 CFR 888.3353
Class II
Product Codes: LZO
Classification Panel: Orthopedic Products Panel
Reviewing Branch: Orthopedic Devices Branch

INTENDED USE

The Bencox Forte and Bencox Delta ceramic heads is intended for use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

- a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis
- b. Inflammatory degenerative joint disease, such as rheumatoid arthritis

- c. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- d. Patients with failed previous surgery where pain, deformity, or dysfunction persists
- e. Revision of previously failed hip arthroplasty

DEVICE DESCRIPTION

The Bencox BioloX Ceramic Head is a component of a Hip Prosthesis System and intended for mechanical fixation to a mating hip stem, with a standard 12/14 taper. It is intended to articulate between both Highly Cross Linked UHMWPE as well as Conventional UHMWPE.

The Bencox Ceramic Head is available as standard type and is manufactured from bio-inert alumina ceramic, Al_2O_3 as per ASTM F603 / ISO 6474. The ceramic femoral balls heads range in diameter from 28 mm to 40 mm with small, medium & large versions.

Radiation (gamma) sterilization is used for Bencox Forte and Bencox Delta BioloX ceramic heads. Sterilization by Co-60 gamma irradiation has been validated to a sterility assurance level (SAL) of 10^{-6} by the bioburden method, according to ISO 11137-1 & ISO 11137-2. Following sterilization packaging was validated for a shelf life of 5 years for BENCOX Forte & Delta ceramic femoral heads.

SUBSTANTIAL EQUIVALENCE TO MARKETING DEVICES

BENCOX Forte & BENCOX Delta BioloX components are substantially equivalent in indications and design principles to the predicate devices, each of which has been determined by FDA to be substantially equivalent:

- MEDACTA International SA; MectaCer BIOLOX forte Femoral Heads cleared under K073337,
- DePuy Orthopedics, Inc., DePuy Delta Ceramic Femoral Head cleared under K062748,
- Corentec Co., Ltd., Coren Total Hip System & Bencox Bipolar Cup System cleared under K103431 & K112019 (*Femoral Heads*).

PERFORMANCE TESTING

Performance testing of the Bencox Forte/Delta Femoral Heads was conducted in accordance with the international standards. All required testing per "Guidance Document for the Preparation of Premarket Notifications of Ceramic Ball Hip Systems" were performed.

- Component testing of BIOLOX forte ball head 28-12/14 L on titanium test tapers per CeramTec AG test procedure VA 02 04 4129, ISO 7206-10.
- Influence of diameter and neck length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14. Burst test setup as per ISO 7206-10.
- Sterilization validation as per ISO 11137 – 1 & 2 Sterilization of health care products – Radiation.

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy of the BENCOX Forte & BENCOX Delta Biolox components for its intended use.

Overall, the BENCOX Forte & BENCOX Delta Biolox components have the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or similar materials, and
- has similar packaging and sterilized using the same materials and processes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Re: K121665

Trade/Device Name: BENCOX[®] Forte & BENCOX[®] Delta

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous
uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: August 28, 2012

Received: August 30, 2012

Dear Mr. Daniel

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE**510(k) Number** (if known): K121665 (pg 1/1)**Device Name:** BENCOX Forte & BENCOX Delta

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- e) Revision of previously failed hip arthroplasty.


Prescription Use: X
(Per 21 CFR 801 Subpart D)

AND / OR

Over-The Counter Use: _____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121665

Corentec Co. Ltd